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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------|------------------|
| 10/664,236 | 09/17/2003 | Sandra M. Maclean | 11842/US/2 | 5239 |
| 7590 | 10/19/2005 | | EXAMINER HILL, LAURA C | |
| S. Wade Johnson DORSEY & WHITNEY LLP Intellectual Property Department 50 South Sixth Street, Suite 1500 Minneapolis, MN 55402-1498 | | | ART UNIT | PAPER NUMBER |
| | | | 3761 | |

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/664,236

Applicant(s)

MACLEAN ET AL.

Examiner

Laura C. Hill

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 10-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6 September 2005.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 6 October 2005 was recorded electronically after the completion of the first action on the merits on 6 October 2005. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Claim Objections

3. Claims 6-9 are objected to because of the following informalities: it is unclear what is meant by 'the use of items in helping the human deal with discharged body fluids.'

Appropriate correction is required.

Claim Language Interpretation

4. The term 'items' as recited in claims 6-9 includes a plurality or more than one item.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the 'miscarriage kit'. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to reproduce the miscarriage kit the invention commensurate in scope with these claims. Specifically, the 'miscarriage kit' could be any available collection of items capable of being used to deal with a miscarriage or collection of bodily fluids.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Schumacher (US 4,917,238; herein 'Schumacher'). Regarding claims 1-4 Schumacher discloses a waste cleanup/miscarriage kit 10 for cleaning up body waste such as vomit, blood, feces and the like (col. 2, ll. 6-7, figure 1) comprising a scoop/specimen pan 80 and container 64 capable of holding pregnancy remains or any other substance (col. 3, ll. 1-3 and line 33).

Regarding claims 5-9 Schumacher discloses label/list 63 (col. 2, ll. 64-68); disposable towels 50, 51, 52 (col. 2, ll. 45-47); two plastic bags 53,54 (col. 4, ll. 47-48);

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disposable plastic gloves 57,58 (col. 2, ll. 52-53); absorbent material 62 (col. 2, ll. 54-55), germicidal hand wipe 7 and scraper 90 (col. 3, lines 25 and 33-34).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Aruffo et al. (US 6,579,271) is cited for showing a post surgery drain kit with measuring cups/container and specimen pan 14, contents map/list 36, gauze pads 16, adhesive tape remover pads 18, pencil 22, soap 24, tape 26, belt bags 28 and drain labels 30. Sangha et al. (US 2003/0012701) is cited for showing a specimen sampling kit 10 with vial/specimen pan 31, waste bag/container 48, information card 46, alcohol pad 34, funnel 33, bandage 42, envelope 49, labels 52a and 52b, absorbent 54 and securing sleeve 50. Burgess (US 2003/0136704) is cited for showing a sanitary napkin kit with panties 13, sanitary napkins and/or tampons, moist hand towels 18. Misra (US 6,012,586) is cited for showing a medical procedure kit used in angiographic procedures with needles, drugs, gowns, balloons, wires, stents, and clips. Higson (US 5,515,974) is cited for showing an emergency and security kit 10 with plastic case/container 12, instructions, flashlight 16, fire extinguisher 30, radio 18, first aid kit 20, candles 22, battery 24, flares, whistles and air horn 26, and security spray 28. Finkel et al. (US 4,702,378) is cited for showing a disposable kit used for baby changing or other purposes with container/specimen pan 16,18,20, labels/list 12, coupons 70, disposable towel/container 108, disposable razor, comb, toothbrush and soap. Mathis (US 4,205,869) is cited for showing animal litter collecting box with scraper 26, bag/liner 24 and twist tie 25. Stoner (US 5,244,096) is cited for showing an STD-prevention kit 10

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with condom 30, instructions 31, toothbrush 35 and four solution containers 36,37,38 and 39. Nieves (US 5,261,531) is cited for showing a sanitary kit 10 with sanitary napkin/container 26, impermeable envelope/pan 12, instructions 16, dry wipe 20, and moistened paper towel 26.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura C. Hill
Examiner
Art Unit 3761

LCH



TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER



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10-664-236

EXAMINER

ART UNIT

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20051006

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Commissioner for Patents